



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

January 5, 2015

Alphatec Spine, Incorporated  
Ms. Renée L. Murphy  
Senior Regulatory Affairs Specialist  
5818 El Camino Real  
Carlsbad, California 92008

Re: K143149  
Trade/Device Name: Arsenal™ Spinal Fixation System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class III  
Product Code: NKB, OSH, MNI, MNH  
Dated: December 5, 2014  
Received: December 8, 2014

Dear Ms. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Lori A. Wiggins -S**

for  
Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K143149

Device Name

Arsenal Spinal Fixation System

Indications for Use (Describe)

The Arsenal Spinal Fixation System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. Fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

When used for posterior non-cervical screw fixation in pediatric patients, the Arsenal Spinal Fixation System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally the Arsenal Spinal Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis / spondylolysis, and fracture caused by tumor and/or trauma. Pediatric pedicle screw fixation is limited to a posterior approach.

The Arsenal Spinal Fixation System is intended to be used with autograft and/or allograft.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## **510(k) Summary**

### **I. SUBMITTER**

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Phone: (760) 431-9286  
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Contact Person: Renée L. Murphy  
Date Prepared: December 4, 2014

### **II. DEVICE**

*Name of Device:* Arsenal™ Spinal Fixation System  
*Common or Usual Name:* Pedicle Screw System  
*Classification Name:* Pedicle screw spinal system (21 CFR 888.3070)  
*Regulatory Class:* III  
*Product Code:* NKB, OSH, MNI, MNH

### **III. PREDICATE DEVICE**

Zodiac Spinal Fixation System, K100685 (Primary Predicate)  
Arsenal Spinal Fixation System, K133221

### **IV. DEVICE DESCRIPTION**

The CBx screws are to be included in the currently marketed Arsenal Spinal Fixation System which is intended for posterior, non-cervical, spinal fixation as an adjunct to fusion for the treatment of degenerative disease, deformity, and trauma indications. The Arsenal System consists of a variety of shapes and sizes of screws, rods, and connectors that provide temporary internal fixation and stabilization during bone graft healing and/or fusion mass development. The CBx screws are made of Titanium Alloy (Ti 6Al 4V ELI) and are designed for placement in the cortical areas of the pedicle where the bone is typically harder, stronger and stiffer than the cancellous portion of the pedicle/vertebra. The threadform of the CBx screws allows the surgeon to use the screw that best suits the patient's anatomy where either cortical bone or *both* cortical bone and cancellous bone are present.

## **V. INDICATIONS FOR USE**

The Arsenal Spinal Fixation System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. Fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

When used for posterior non-cervical screw fixation in pediatric patients, the Arsenal Spinal Fixation System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally the Arsenal Spinal Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis / spondylolysis, and fracture caused by tumor and/or trauma. Pediatric pedicle screw fixation is limited to a posterior approach.

The Arsenal Spinal Fixation System is intended to be used with autograft and/or allograft.

## **VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES**

The technological design features of the CBx screws are similar to the predicate screws of the Zodiac and Arsenal Spinal Fixation Systems. Both are pedicle screw systems and are intended for posterior non-cervical screw fixation as an adjunct to fusion. The CBx screws are also similar to the predicates in that they have the same technical characteristics in terms of design, materials, threadform, componentry and assembly.

The differences between the subject CBx screws and the predicates are minor and do not raise any new or different questions regarding safety and effectiveness.

## **VII. PERFORMANCE DATA**

The following mechanical performance information is being provided in support of a substantial equivalence determination.

The CBx screw and the predicates underwent mechanical performance testing per “*Guidance for Industry and FDA Staff: Spinal Systems 510(k)’s, May 3, 2004*”. Specific tests that were conducted for which a determination of substantial equivalence is claimed are listed on the next page:

#### ASTM F1717

- Static Compression Bending Test
- Dynamic Compression Bending Test
- Static Torsional Test

#### ASTM F1798

- Flexion extension moment ( $M_y$ )
- Flexion extension moment fatigue run out ( $M_y$ )

Test results demonstrate that the performance and functionality of the CBx screws are substantially equivalent to the Zodiac System and Arsenal System screws.

### **VIII. CONCLUSION**

Based upon the information provided in this Special 510(k) submission, it has been determined that the CBx screw is substantially equivalent to the predicate devices in regards to the following:

- Indications for Use,
- Fundamental Scientific Technology,
- Materials,
- Labeling and packaging, and
- Performance Characteristics.

The CBx screw and the predicates were subjected to the same tests using the same methods under the same conditions. The CBx test results and analysis demonstrate substantial equivalence to the predicate devices.